



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB77

Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved Accreditor Processes

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: Under the authority granted to the National Coordinator for Health Information Technology by section 3001(c)(5) of the Public Health Service Act (PHSA) as added by the Health Information Technology for Economic and Clinical Health (HITECH) Act, this final rule establishes a process for addressing instances where the ONC-Approved Accreditor (ONC-AA) engages in improper conduct or does not perform its responsibilities under the permanent certification program. This rule also addresses the status of ONC-Authorized Certification Bodies (ONC-ACBs) in instances where there may be a change in the accreditation organization serving as the ONC-AA and clarifies the responsibilities of the new ONC-AA.

DATES: These regulations are effective [INSERT DATE - 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Acronyms

CMS	Centers for Medicare & Medicaid Services
EHR	Electronic Health Record
HHS	Department of Health and Human Services
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health
ONC	Office of the National Coordinator for Health Information Technology
ONC-AA	ONC-Approved Accreditor
ONC-ACB	ONC-Authorized Certification Body
ONC-ATCB	ONC-Authorized Testing and Certification Body
PHSA	Public Health Service Act
RFA	Regulatory Flexibility Act
SBA	Small Business Administration

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I. Background

A. Statutory Basis for the Permanent Certification Program

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5), amended the Public Health Service Act (PHSA) to add a new “Title XXX – Health Information Technology and Quality.” Section 3001(c)(5) of the PHSA, as added by section 13101 of the HITECH Act, provides the National Coordinator for Health Information Technology (National Coordinator) with the authority to establish a certification program or programs for the voluntary certification of health information technology (HIT). Specifically, section 3001(c)(5)(A) states that the “National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under [section 3004 of the PHSA].”

B. Regulatory Background of the Permanent Certification Program

1. Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology; Interim Final and Final Rules

In accordance with section 3004(b)(1) of the PHSA, the Secretary of Health and Human Services (the Secretary) issued an interim final rule with a request for comment entitled “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” (75 FR 2014, Jan. 13, 2010) (the “HIT Standards and Certification Criteria interim final rule”), which adopted an initial set of standards, implementation specifications, and certification criteria. After consideration of the public comments received on the interim final rule, a final rule entitled “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” (75 FR 44590) (the “HIT Standards and Certification Criteria final rule”) was issued on July 28, 2010 to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for meaningful use Stage 1. On October 13, 2010, an interim final rule (75 FR 62686) was issued to remove certain implementation specifications related to public health surveillance that had been previously adopted in the HIT Standards and Certification Criteria final rule.

The standards, implementation specifications, and certification criteria adopted by the Secretary establish the capabilities that Certified Electronic Health Record (EHR) Technology must include in order to, at a minimum, support the achievement of meaningful use Stage 1 by eligible professionals and eligible hospitals¹ under the Medicare and Medicaid EHR Incentive Programs.

2. Medicare and Medicaid EHR Incentive Programs Proposed and Final Rules

¹ References to “eligible hospitals” in this rule shall mean “eligible hospitals and/or critical access hospitals, as defined in 42 CFR 495.4” unless otherwise indicated.

Associated with the HIT Standards and Certification Criteria interim final rule, the Centers for Medicare & Medicaid Services (CMS) concurrently published in the Federal Register (75 FR 1844, Jan. 13, 2010) the Medicare and Medicaid Electronic Health Record Incentive Programs proposed rule. The rule proposed a definition for Stage 1 meaningful use of Certified EHR Technology and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act. Subsequently, CMS published a final rule for the Medicare and Medicaid EHR Incentive Programs in the Federal Register (75 FR 44314) on July 28, 2010, simultaneously with the publication of the HIT Standards and Certification Criteria final rule. The final rule, published by CMS, established the objectives and associated measures that eligible professionals and eligible hospitals must satisfy in order to demonstrate “meaningful use” during Stage 1.

3. HIT Certification Programs Proposed Rule and the Temporary and Permanent Certification Programs Final Rules

Based on the authority provided in section 3001(c)(5) of the PHSA, we proposed both a temporary and permanent certification program for HIT in a notice of proposed rulemaking entitled "Proposed Establishment of Certification Programs for Health Information Technology" (75 FR 11328, Mar. 10, 2010). We proposed to use the certification programs for the purposes of testing and certifying HIT and specified the processes the National Coordinator would follow to authorize organizations to perform the testing and/or certification of HIT. Notably, we issued two final rules to implement our proposals. On June 24, 2010, a final rule was published in the Federal Register (75 FR 36158) to establish a temporary certification program (the “Temporary

Certification Program final rule”). On January 7, 2011, a final rule was published in the Federal Register (76 FR 1262) to establish the permanent certification program (the “Permanent Certification Program final rule”). The permanent certification program will eventually replace the temporary certification program, which included a sunset provision (45 CFR 170.490) that specified it would sunset on December 31, 2011 or on a subsequent date if the permanent certification program is not fully constituted at that time.

EHR technology that is tested and certified under the certification programs currently must be tested and certified in accordance with all applicable certification criteria adopted by the Secretary under section 3004(b)(1) of the PHSA and could potentially be used to satisfy the definition of Certified EHR Technology. Eligible professionals and eligible hospitals that successfully demonstrate meaningful use of Certified EHR Technology may receive incentive payments under the Medicare and Medicaid EHR Incentive Programs.

4. ONC-AA Processes Proposed Rule

On May 31, 2011, a proposed rule entitled “Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved Accreditor Processes” was published in the Federal Register (76 FR 31272) (the “Proposed Rule”). As described further in the section of this final rule entitled “Summary of the Proposed Rule and Provisions of the Final Rule,” we proposed a removal process for addressing instances where the ONC-AA engages in improper conduct or does not perform its responsibilities under the permanent certification program. We also made proposals and clarifications concerning instances where the accreditation organization serving as the ONC-AA

changes, the effect that such a change would have on the status of ONC-ACBs, and the responsibilities of the new ONC-AA.

C. Overview of the Permanent Certification Program

Key facets of the permanent certification program are summarized as follows. The permanent certification program provides a process by which an organization or organizations may become authorized by the National Coordinator to perform the certification of Complete EHRs and/or EHR Modules as an ONC-Authorized Certification Body (ONC-ACB). ONC-ACBs may also be authorized under the permanent certification program to perform the certification of other types of HIT in the event that the Secretary adopts applicable certification criteria. We note, however, that the certification of Complete EHRs, EHR Modules, or potentially other types of HIT under the permanent certification program would not constitute a replacement or substitution for other Federal requirements that may be applicable.

An organization that seeks to become an ONC-ACB must, among other requirements, successfully obtain accreditation from the accreditation organization that has been approved by the National Coordinator as the ONC-Approved Accreditor (ONC-AA). Only one accreditation organization at a time may be approved to serve as the ONC-AA. An accreditation organization that wishes to be considered for ONC-AA status must submit a written request to the National Coordinator during the specified submission period and include certain information to demonstrate its ability to serve as the ONC-AA. The National Coordinator will determine which accreditation organization is best qualified to serve as the ONC-AA, and the organization that is approved on a final basis will be expected to serve a three-year term. The ONC-AA must fulfill certain on-

going responsibilities for the permanent certification program, which include: maintaining conformance with ISO/IEC 17011:2004 (ISO 17011); in accrediting certification bodies, verifying that they conform to ISO/IEC Guide 65:1996 (Guide 65) at a minimum; and performing certain activities related to surveillance that will be conducted by ONC-ACBs.

On February 8, 2011, ONC published a notice in the Federal Register (76 FR 6794) announcing a 30-day period for the submission of requests for ONC-AA status. After the close of the submission period, the National Coordinator reviewed all timely submissions that were received and determined which accreditation organization was best qualified to serve as the ONC-AA based on the information provided, the completeness of each accreditation organization's description of the elements listed in § 170.503(b), and each accreditation organization's overall accreditation experience. On June 9, 2011, ONC announced through our listserv and website that the American National Standards Institute (ANSI) had been approved by the National Coordinator as the ONC-AA for the permanent certification program.

The National Coordinator will accept applications for ONC-ACB status at any time, which must include the type of authorization sought, general identifying information, documentation that confirms that the applicant has been accredited by the ONC-AA, and an executed agreement that it will adhere to the Principles of Proper Conduct for ONC-ACBs in 45 CFR 170.523. ONC-ACBs will be required to remain in good standing by, among other things, adhering to the Principles of Proper Conduct for ONC-ACBs, which include a requirement that an ONC-ACB must maintain its accreditation that was granted by the ONC-AA. An ONC-ACB's status will expire in

three years, unless its status is renewed. The National Coordinator may revoke an ONC-ACB's status and/or suspend an ONC-ACB's operations under the permanent certification program, based on Type-1 and Type-2 violations.

II. Summary of the Proposed Rule and Provisions of the Final Rule

The public comment period for the Proposed Rule ended on August 1, 2011. We received no comments on the Proposed Rule during that period. In this section, we summarize the proposals that we made in the Proposed Rule and discuss the provisions that we are finalizing in this final rule.

A. Removal of the ONC-AA for Improper Conduct or Failure to Perform Its Responsibilities

In the proposed rule to establish the temporary and permanent certification programs (75 FR 11328), we did not propose a formal process for the National Coordinator to remove or take other corrective action against an accreditation organization serving as the ONC-AA based on misconduct or failure to perform its responsibilities. We did propose and finalize a process through which the National Coordinator could revoke the status and/or suspend the operations of an ONC-Authorized Testing and Certification Body (ONC-ATCB) under the temporary certification program and an ONC-ACB under the permanent certification program. Some of the comments we received asked how we would address concerns with an ONC-AA's operations and remove or replace an ineffective ONC-AA. We responded to those comments in the Permanent Certification Program final rule (76 FR 1269) by stating our intentions to issue a notice of proposed rulemaking that would address improper conduct by an ONC-AA, the potential consequences for engaging in such conduct, and a process by which the

National Coordinator may take “corrective action” against an ONC-AA. We followed through with our intentions by issuing the Proposed Rule.

In the Proposed Rule, we proposed a process for removing the ONC-AA for improper conduct or failure to perform its responsibilities under the permanent certification program. The process we proposed is similar to the process established in the Permanent Certification Program final rule for suspending and/or revoking an ONC-ACB’s status. We recognize that an ONC-AA has significant responsibilities under the permanent certification program that are inextricably linked to the success of the program. Furthermore, a removal process would protect the integrity of the permanent certification program and maintain public confidence in the program by removing an ONC-AA that engages in misconduct or fails to satisfy its performance obligations under the program. We are finalizing our proposal to establish a process for removing the ONC-AA for conduct and performance violations, as explained below.

1. Conduct Violations

We proposed that the National Coordinator could remove an ONC-AA for committing a conduct violation. We proposed that conduct violations would include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program, such as false, fraudulent, or abusive activities that affect the permanent certification program, a program administered by the Department of Health and Human Services (HHS), or any program administered by the Federal government.

We gave the following examples of conduct violations in the Proposed Rule: the ONC-AA (or a principal employee, owner, or agent of the ONC-AA) being charged

with or convicted of fraud, embezzlement or extortion, or of violating similar Federal or State securities laws while participating in the permanent certification program; falsifying accreditations; or withholding, destroying, or altering information that would indicate false or fraudulent activity had occurred within the permanent certification program.

We proposed these types of violations as conduct violations because, as the definition of conduct violations specifies, they threaten or significantly undermine the integrity of the permanent certification program, which can negatively impact the overall success of the program. These violations are also consistent with the “Type-1 violations” we previously established for ONC-ACBs under the permanent certification program. Because our approach establishes consistency within the permanent certification program in terms of comparable conduct requirements for the ONC-AA and ONC-ACBs, we believe that it will ensure that all of the entities approved and authorized by ONC are held accountable for their conduct. Accordingly, we are finalizing the conduct violations as proposed at § 170.575(a).

2. Performance Violations

We proposed that the National Coordinator could remove an ONC-AA for failing to timely or adequately correct a performance violation. We proposed that performance violations would include the ONC-AA’s failure to properly fulfill one or more of its responsibilities in § 170.503(e). These responsibilities include the following: maintaining conformance with ISO 17011; in accrediting certification bodies, verifying conformance to, at a minimum, Guide 65 and ensuring the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods; verifying that ONC-ACBs are performing surveillance in accordance with their respective annual plans;

and reviewing ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by the ONC-ACBs with the conditions of their respective accreditations.

We noted in the Proposed Rule that opportunities to assess an ONC-AA's performance of its responsibilities will be available at certain junctures during the permanent certification program. For example, our review of an ONC-ACB's surveillance results should give an indication of whether the ONC-AA is performing its responsibilities to review ONC-ACB surveillance results and verify that ONC-ACBs are performing surveillance in accordance with their surveillance plans. Further, we expect that our review and analysis of surveillance plans and results will not only include feedback from the ONC-ACBs but also feedback from the ONC-AA. The ONC-AA feedback will provide us with additional information on the ONC-AA's performance of its responsibilities to monitor and review ONC-ACBs' surveillance activities.

We also indicated in the Proposed Rule that the National Coordinator could obtain information about the ONC-AA from other sources as well. For example, the National Coordinator could potentially receive information from an organization that sought accreditation by the ONC-AA and was denied, or from an ONC-ACB that had its accreditation withdrawn by the ONC-AA. Such information could provide reliable evidence that the ONC-AA was not in compliance with ISO 17011, as required by § 170.503(e)(1). To illustrate, section 7 (Accreditation process) of ISO 17011 requires the ONC-AA to establish a proper assessment process for accrediting conformance assessment bodies (i.e., certification bodies or ONC-ACBs), which includes establishing procedures to address appeals by such bodies. Information from a certification body that

sought accreditation or an ONC-ACB could indicate whether the ONC-AA had a sufficient assessment or appeals processes in place.

We proposed that if the National Coordinator obtains reliable evidence from fact-gathering, requesting information from the ONC-AA, contacting the ONC-AA's customer(s), and/or complaints that the ONC-AA is not properly performing its responsibilities under § 170.503(e), the National Coordinator would notify the ONC-AA of an alleged performance violation. We proposed that the notification would include all pertinent information regarding the National Coordinator's assessment. We proposed that, unless otherwise specified by the National Coordinator, the ONC-AA would be permitted up to 30 days from the date it is notified about the alleged performance violation(s) to submit a written response and any accompanying documentation that could demonstrate no violation(s) occurred or validate that violation(s) occurred and were corrected. We proposed that if the ONC-AA fails to submit a response to the National Coordinator within 30 days, the National Coordinator may issue the ONC-AA a notice proposing to remove it as the ONC-AA under the permanent certification program.

We further proposed that if the ONC-AA submits a response, the National Coordinator would be permitted up to 60 days to evaluate the ONC-AA's response (and request additional information, if necessary). If the National Coordinator determines that the ONC-AA did not commit a performance violation, or may have committed a performance violation but satisfactorily corrected any violation(s) that may have occurred, we proposed that a memo would be issued to the ONC-AA to confirm this determination. If the National Coordinator determines that the ONC-AA's response is

insufficient and that a performance violation had occurred and had not been adequately corrected, then the National Coordinator may propose to remove the ONC-AA.

As previously mentioned, the ONC-AA has significant responsibilities under the permanent certification program. The failure of the ONC-AA to perform any of its responsibilities could not only affect the success of the permanent certification program but, if left unchecked, could cause the public to lose faith in the ONC-ACBs accredited by the ONC-AA and ultimately the certifications issued by those ONC-ACBs. For example, if the ONC-AA does not fulfill its responsibilities to verify that ONC-ACBs are performing surveillance in accordance with their respective annual plans or does not review ONC-ACBs' surveillance results to determine if the results indicate any substantive non-conformance by ONC-ACBs with the conditions of their respective accreditations, then the public may not have faith in the validity of the surveillance results, including the reliability of the certifications issued to EHR technology by ONC-ACBs.

Although the ONC-AA's failure to perform its responsibilities could, if left unchecked, have negative consequences as illustrated above, the ONC-AA should be given the opportunity to either correct its performance shortcomings or demonstrate that it did not fail to perform its responsibilities within a reasonable period of time that does not jeopardize the success of the permanent certification program. The opportunity to respond to a noncompliance notification provides such an opportunity and does so within a timeframe that permits the National Coordinator to reach a timely and reasoned determination on whether to propose the removal of the ONC-AA. If the National Coordinator determines that the ONC-AA is not properly performing its responsibilities

under § 170.503(e), then we continue to believe that proposing the removal of the ONC-AA is the best course of action to take to protect the integrity of the permanent certification program and maintain public trust in the program. We are finalizing the proposed performance violations at § 170.575(b) and the processes related to noncompliance notification as proposed at § 170.575(b)(1) and (2).

3. Proposed Removal of the ONC-AA

We proposed that if the National Coordinator has reliable evidence that the ONC-AA committed one or more conduct violations, or if the ONC-AA fails to successfully rebut or submit a response to a noncompliance notification of an alleged-performance violation, then the National Coordinator may issue the ONC-AA a notice proposing to remove it as the ONC-AA under the permanent certification program. In the Proposed Rule, we noted our opinion that proposing to remove the ONC-AA would be more appropriate than suspending the ONC-AA's activities under the permanent certification program. Any form of suspension would prevent the ONC-AA from performing its responsibilities under § 170.503(e), which would not benefit the permanent certification program because these ongoing responsibilities are an integral part of the program. Having received no comments to the contrary, we continue to believe that proposing removal under the circumstances described in the Proposed Rule and this final rule would be preferable to suspension. We are finalizing the proposed removal process in § 170.575(c) as proposed.

4. Opportunity To Respond to a Proposed Removal Notice

We proposed that if the National Coordinator issues a proposed removal notice to the ONC-AA, the ONC-AA must respond within 20 days of receipt of the removal notice

in order to contest the proposed removal and must provide sufficient documentation to support its explanation for why it should not be removed. Upon receipt of the ONC-AA's response to a proposed removal notice, we proposed that the National Coordinator would be permitted up to 60 days to review the information submitted by the ONC-AA and make a determination. We conveyed our expectations that during the time period provided for the ONC-AA to respond to the proposed removal notice and the National Coordinator's review period, the ONC-AA would continue to perform its responsibilities under the permanent certification program. We proposed that the National Coordinator would consider the ONC-AA's performance of its duties during this timeframe as a factor in reaching any final decision to remove the ONC-AA.

We believe that our proposed process and timeframes provide an appropriate opportunity for the ONC-AA to respond to a proposed removal notice. In a situation where removal is proposed, an ONC-AA will have been issued a proposed removal notice that sets forth the conduct violations committed by the ONC-AA or specifies that the ONC-AA failed to respond to a non-compliance notification or correct performance violations. At such a juncture, the ONC-AA would already be jeopardizing the integrity of the permanent certification program if it had committed conduct violations and would be doing the same if it had failed to timely reply to a non-compliance notification or address performance violations after receiving a non-compliance notification. Therefore, 20 days provides the ONC-AA sufficient opportunity to respond to the proposed removal notice, while also bringing about a timely resolution in the interest of the permanent certification program. The National Coordinator will have up to 60 days to issue a final decision. This timeframe gives the National Coordinator the ability to issue a timely

decision where the information is clear that the ONC-AA committed a conduct violation and the permanent certification program's integrity is increasingly at risk the longer the accreditation organization serving as the ONC-AA is allowed to remain in its position. The timeframe also provides the National Coordinator sufficient time to address complications or complexities related to reaching a final decision on whether to remove the ONC-AA. Therefore, we are finalizing this process and the associated timeframes in § 170.575(d) as proposed.

5. Removal of the ONC-AA

We proposed that the ONC-AA may be removed by the National Coordinator if it is determined that removal is appropriate after considering the information provided by the ONC-AA in response to the proposed removal notice or if the ONC-AA does not respond to a proposed removal notice within the specified timeframe. We proposed that a decision to remove the ONC-AA would be final and would not be subject to further review unless the National Coordinator chooses to reconsider the removal.

We further proposed that if the National Coordinator determines that the ONC-AA should not be removed, the National Coordinator would notify the ONC-AA in writing to express this determination.

We received no comments on this proposal and thus continue to believe that removing the ONC-AA from the permanent certification program would be an appropriate course of action in response to the conduct and performance violations that we are establishing in this final rule. Accordingly, we are finalizing the standard for removing the ONC-AA as proposed at § 170.575(f). We are also finalizing § 170.575(e)

as proposed such that the ONC-AA will be notified if the National Coordinator determines that the ONC-AA should not be removed.

6. Extent and Duration of Removal Under the Permanent Certification Program

We proposed that the removal of the ONC-AA would become effective upon the date specified in the removal notice and that the affected accreditation organization would be required to cease all activities under the permanent certification program, including accepting new requests for accreditation associated with the permanent certification program. We further proposed that an accreditation organization that has been removed as the ONC-AA will be prohibited from being considered for ONC-AA status for a period of 1 year from the effective date of removal.

Violation(s) committed by the accreditation organization serving as the ONC-AA which result in its removal demonstrate that it cannot conduct itself properly or perform its responsibilities under the permanent certification program. Accordingly, we believe it would be inappropriate to permit an accreditation organization that has been removed from the permanent certification program as the ONC-AA to reapply immediately to become the new ONC-AA. We, therefore, proposed a 1-year waiting period to prevent the accreditation organization that has been removed from being considered when ONC goes through the process in § 170.503 to approve its replacement. Having received no comments to the contrary, we continue to believe that removal should be effective upon the date specified in the removal notice, that the removed ONC-AA should cease all activities under the permanent certification program, and that, for the reason noted, one year is a reasonable period of time for an accreditation organization to wait before it may

reapply to become the ONC-AA. We are finalizing these provisions in § 170.575(g) as proposed.

B. Effects of Removing and/or Replacing the ONC-AA

1. ONC-ACB Status

In § 170.523(a) we require that an ONC-ACB “[m]aintain its accreditation.” As we indicated in the Proposed Rule, it is possible that during the course of an ONC-ACB’s three-year term, there could be a change in accreditation organizations serving as the ONC-AA. In other words, the accreditation organization serving as the ONC-AA that initially accredited an ONC-ACB could be replaced by a different accreditation organization that is subsequently approved to serve as the ONC-AA. A change in ONC-AAs could occur under different scenarios, such as if the accreditation organization serving as the ONC-AA resigns before the end of its term, is replaced at the end of its term through the selection process under § 170.503, or is removed by the National Coordinator before the end of its term. We proposed that if there is a change in accreditation organizations serving as the ONC-AA, such as in the scenarios described above, an ONC-ACB would retain its status under the permanent certification program, but only for a reasonable period of time to allow it to obtain accreditation from the accreditation organization that is approved as the new ONC-AA. This would support our primary goal of ensuring stability among ONC-ACBs and within the HIT marketplace, which would include the uninterrupted certification of HIT.

We proposed that an ONC-ACB must obtain accreditation from the new ONC-AA within 12 months after the effective date of the new ONC-AA’s status or within a reasonable period specified by the National Coordinator. We use the term “effective

date” because although an accreditation organization could be approved as the ONC-AA pursuant to the process in § 170.503, its status as the ONC-AA may not become effective until a later date (e.g., its status may not take effect until the then-current ONC-AA’s term expires). Based on our consultations with subject matter experts at the National Institute for Standards and Technology (NIST), we stated our belief in the Proposed Rule that a new ONC-AA could complete the accreditation process for up to 6 ONC-ACBs within 6 to 9 months. We noted that this could possibly be an appropriate timeframe and could be sufficient to meet the demand for accreditation considering that we estimated in the Permanent Certification Program final rule that only 6 ONC-ACBs will be operating under the permanent certification program and only 6 ONC-Authorized Testing and Certification Bodies (ONC-ATCBs) are currently operating under the temporary certification program. However, considering that there may be more ONC-ACBs than we anticipated and that accreditation to the requirements of a new ONC-AA may require more time than anticipated, we proposed that 12 months would be a more reasonable timeframe for ONC-ACBs to obtain accreditation from the new ONC-AA.

We emphasized that our proposal permits the National Coordinator to specify a reasonable period of time for ONC-ACBs to obtain accreditation from the new ONC-AA as an alternative to the 12-month timeframe. We noted that it would be prudent for the National Coordinator to have the flexibility to grant an extension to an ONC-ACB if it had filed a request for accreditation with the new ONC-AA before the 12-month timeframe had elapsed and the new ONC-AA had not yet completed its accreditation of the ONC-ACB. Alternatively, there may be a need for the National Coordinator to require that ONC-ACBs obtain accreditation from the new ONC-AA in less than 12

months to protect the integrity of the permanent certification program. This situation could occur if the accreditation organization removed as the ONC-AA engaged in conduct that called into question the legitimacy of the accreditations granted to ONC-ACBs.

The 12-month period provides sufficient time for the orderly yet timely accreditation of the ONC-ACBs by the new ONC-AA. It also ensures that ONC-ACBs are treated fairly. Such as the case where an ONC-ACB, in good faith and without sufficient notice of a possible change in the ONC-AA, recently paid for and obtained accreditation from an ONC-AA that is subsequently removed or replaced. The discretion provided to the National Coordinator ensures the program's stability by permitting the 12-month period to be extended if needed to complete ONC-ACBs' accreditations. It also ensures the program's stability and integrity by providing the option to require ONC-ACBs to be accredited in less than 12 months if, for instance, the veracity of the ONC-ACBs' prior accreditations are called into question. As proposed, we are revising § 170.523(a) to require an ONC-ACB to "[m]aintain its accreditation, or if a new ONC-AA is approved by the National Coordinator, obtain accreditation from the new ONC-AA within 12 months or a reasonable period specified by the National Coordinator and maintain such accreditation."

2. New ONC-AA

As noted above, the National Coordinator may approve a new accreditation organization as the ONC-AA for reasons such as the former ONC-AA resigning, another accreditation organization being selected when the former ONC-AA's term expires, or the former ONC-AA being removed for conduct or performance violations. The

selection and approval of a new ONC-AA would be conducted as soon as possible and consistent with the processes and timeframes in § 170.503. Doing so would permit the new ONC-AA to begin fulfilling its responsibilities under § 170.503(e) when its status as the ONC-AA becomes effective. In the Proposed Rule, we explained that a new ONC-AA would be expected to fulfill its responsibilities under § 170.503(e) with respect to the ONC-ACBs that it accredited, as well as those ONC-ACBs that were accredited by the former ONC-AA and are not yet accredited by the new ONC-AA. The new ONC-AA would be responsible for verifying that all ONC-ACBs are performing surveillance in accordance with their respective annual plans, as required by § 170.503(e)(3). In addition, consistent with § 170.503(e)(4), the new ONC-AA would review all ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by the ONC-ACBs with the conditions of their respective accreditations (even if an ONC-ACB was accredited by the former ONC-AA).

Section 170.503(e)(2) requires the ONC-AA, “[i]n accrediting certification bodies, [to] verify conformance to, at a minimum, [Guide 65] and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods.” In the Permanent Certification Program final rule (76 FR 1270), we explained this ongoing responsibility would require the ONC-AA to verify that ONC-ACBs continue to conform to the provisions of Guide 65 at a minimum as a condition of continued accreditation. We explained in the Proposed Rule that, similar to 170.503(e)(3) and (e)(4), we would expect a new ONC-AA to fulfill the responsibilities in § 170.503(e)(2) for the certification bodies it accredits and all ONC-ACBs, including those ONC-ACBs that it has not yet had an opportunity to accredit. To clarify this

expectation, we proposed to revise § 170.503(e)(2) to require the ONC-AA to ensure that all ONC-ACBs continue to conform to Guide 65 at a minimum. We made similar clarifying revisions to § 170.503(e)(4) in the Permanent Certification Program final rule (76 FR 1270), where we explained that we were revising § 170.503(e)(4) to account for the possibility that different accreditation organizations may be approved to serve as the ONC-AA. We revised that section to clarify that the ONC-AA would be responsible for reviewing ONC-ACB surveillance results to determine if the results indicated any substantive non-conformance by ONC-ACBs with the conditions of “their respective accreditations” rather than “with the terms set by the ONC-AA when it granted the ONC-ACB accreditation” as we had proposed.

Although our proposals would require a new ONC-AA to become familiar with ONC-ACBs that may not yet have been accredited by the new ONC-AA, we believe the responsibilities in § 170.503(e) would still be achievable. A new ONC-AA would be required by § 170.503(e)(3) to verify that the ONC-ACBs are performing surveillance in accordance with their respective annual plans, which ONC could make available to the new ONC-AA. As for a new ONC-AA’s responsibilities under § 170.503(e)(4), we believe that the former ONC-AA’s accreditation requirements would be publicly available, consistent with section 7.1.2 of ISO 17011, or ONC could provide them to the new ONC-AA along with any surveillance results of the ONC-ACBs. We expect that a new ONC-AA would fulfill these responsibilities in the manner we have described until it has the opportunity to accredit the ONC-ACBs according to Guide 65 at a minimum and its own additional accreditation requirements if applicable. By fulfilling these duties, a

new ONC-AA would contribute to the success of the permanent certification program by ensuring that activities under the permanent certification program continue uninterrupted.

For the reasons discussed above, and because we did not receive any comments on our proposals, we are finalizing our proposed revisions to § 170.503(e). Paragraphs (e)(3) and (e)(4) are redesignated as paragraphs (e)(4) and (e)(5), respectively. Paragraph (e)(2) is revised to state that the ONC-AA shall “[v]erify that the certification bodies it accredits and ONC-ACBs conform to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599).” The second part of paragraph (e)(2) is now a separate new paragraph, which is numbered as (e)(3) and states that the ONC-AA shall “ensure that the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods.”

III. Collection of Information Requirements

This final rule, specifically § 170.575, would only require the collection of information from the ONC-AA if we took an action against the ONC-AA under the provisions of this final rule and the ONC-AA submitted information to ONC in response to the action as provided for under the provisions of this final rule. The Paperwork Reduction Act of 1995, however, exempts the information collection activities referenced in this final rule. Specifically, 44 USC 3518(c)(1)(B)(ii) excludes collection activities during the conduct of administrative actions or investigations involving the agency against specific individuals or entities.

IV. Regulatory Impact Statement

We have examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order

13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule does not reach the economic threshold and thus is not considered a major rule. Therefore, a regulatory impact analysis has not been prepared.

The Regulatory Flexibility Act (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. The entities that will be directly affected by this final rule are likely small businesses in the form of accreditation organizations interested in becoming the ONC-AA, the ONC-AA, potential applicants for ONC-ACB status, and ONC-ACBs. We believe that these entities would either be classified under the North American Industry Classification System (NAICS) codes 541380 (Testing Laboratories) or 541990 (Professional,

Scientific and Technical Services).² According to the NAICS codes identified above, this would mean Small Business Administration (SBA) size standards of \$12 million and \$7 million in annual receipts, respectively.³

We do not believe that this final rule imposes requirements for the ONC-AA that would be unexpected by accreditation organizations interested in serving as the ONC-AA. An accreditation organization serving as the ONC-AA would expect to be required to properly fulfill its responsibilities and exhibit proper conduct or be subject to consequences. Moreover, as noted above, we indicated in prior rulemaking concerning the permanent certification program that we expected to issue a notice of proposed rulemaking and gave a general overview of the topics it would likely address. We believe the processes that we have established constitute the minimum amount of requirements necessary to accomplish our policy goals and that no appropriate regulatory alternatives could be developed to lessen the compliance burden for the ONC-AA. As for ONC-ACBs, this final rule mitigates any potential negative consequences of removing and replacing the ONC-AA, if required. Should the ONC-AA be replaced, this final rule permits ONC-ACBs to retain their status and provides ONC-ACBs up to 12 months or a reasonable period specified by the National Coordinator to obtain accreditation from the new ONC-AA. Furthermore, the established process for addressing instances where the ONC-AA engages in improper conduct or fails to perform its responsibilities under the permanent certification program could create positive effects for program participants by increasing the accountability of the ONC-AA and protecting

² See 13 CFR 121.201

³ The SBA references that annual receipts means “total income” (or in the case of a sole proprietorship, “gross income”) plus “cost of goods sold” as these terms are defined and reported on Internal Revenue Service tax return forms. For more information on the SBA’s size standards, see the SBA’s website at: <http://www.sba.gov/content/small-business-size-regulations>.

the integrity of the permanent certification program. We examined the implications of this final rule and have concluded, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately \$136 million. This final rule will not impose an unfunded mandate on State, local, and tribal governments or on the private sector that will reach the threshold level.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this final rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this final rule was not reviewed by the Office of Management and Budget.

List of Subjects in 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

- For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is amended as follows:

**PART 170 – HEALTH INFORMATION TECHNOLOGY STANDARDS,
IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA
AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION
TECHNOLOGY**

1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

2. In § 170.503, redesignate and republish paragraphs (e)(3) and (e)(4) as paragraphs (e)(4) and (e)(5), revise paragraph (e)(2), and add new paragraph (e)(3) to read as follows:

§ 170.503 Requests for ONC-AA status and ONC-AA ongoing responsibilities.

* * * * *

(e) * * *

(2) Verify that the certification bodies it accredits and ONC-ACBs conform to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599);

(3) Ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;

(4) Verify that ONC-ACBs are performing surveillance in accordance with their respective annual plans; and

(5) Review ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC-ACBs with the conditions of their respective accreditations.

* * * * *

3. In § 170.523, republish the introductory text and revise paragraph (a) to read as follows:

§ 170.523 Principles of proper conduct for ONC-ACBs.

An ONC-ACB shall:

(a) Maintain its accreditation, or if a new ONC-AA is approved by the National Coordinator, obtain accreditation from the new ONC-AA within 12 months or a reasonable period specified by the National Coordinator and maintain such accreditation;

* * * * *

4. Add § 170.575 to read as follows:

§ 170.575 Removal of the ONC-AA.

(a) Conduct violations. The National Coordinator may remove the ONC-AA for committing a conduct violation. Conduct violations include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program. These violations include, but are not limited to: false, fraudulent, or abusive activities that affect the permanent certification program, a program administered by HHS, or any program administered by the Federal government.

(b) Performance violations. The National Coordinator may remove the ONC-AA for failing to timely or adequately correct a performance violation. Performance violations constitute a failure to adequately perform the ONC-AA's responsibilities as specified in § 170.503(e).

(1) Noncompliance notification. If the National Coordinator obtains reliable evidence that the ONC-AA may no longer be adequately performing its responsibilities

specified in § 170.503(e), the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC-AA requesting that the ONC-AA respond to the alleged violation and correct the violation, if applicable.

(2) Opportunity to become compliant. The ONC-AA is permitted up to 30 days from receipt of a noncompliance notification to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC-AA submits a response, the National Coordinator is permitted up to 60 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC-AA during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC-AA confirming this determination. Otherwise, the National Coordinator may propose to remove the ONC-AA in accordance with paragraph (c) of this section.

(c) Proposed removal.

(1) The National Coordinator may propose to remove the ONC-AA if the National Coordinator has reliable evidence that the ONC-AA has committed a conduct violation; or

(2) The National Coordinator may propose to remove the ONC-AA if, after the ONC-AA has been notified of an alleged performance violation, the ONC-AA fails to:

- (i) Rebut the alleged violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or
 - (ii) Submit to the National Coordinator a written response to the noncompliance notification within the specified timeframe under paragraph (b)(2) of this section.
- (d) Opportunity to respond to a proposed removal notice.
 - (1) The ONC-AA may respond to a proposed removal notice, but must do so within 20 days of receiving the proposed removal notice and include appropriate documentation explaining in writing why it should not be removed as the ONC-AA.
 - (2) Upon receipt of the ONC-AA's response to a proposed removal notice, the National Coordinator is permitted up to 60 days to review the information submitted by the ONC-AA and reach a decision.
- (e) Retention of ONC-AA status. If the National Coordinator determines that the ONC-AA should not be removed, the National Coordinator will notify the ONC-AA in writing of this determination.
- (f) Removal.
 - (1) The National Coordinator may remove the ONC-AA if:
 - (i) A determination is made that removal is appropriate after considering the information provided by the ONC-AA in response to the proposed removal notice; or
 - (ii) The ONC-AA does not respond to a proposed removal notice within the specified timeframe in paragraph (d)(1) of this section.

- (2) A decision to remove the ONC-AA is final and not subject to further review unless the National Coordinator chooses to reconsider the removal.
- (g) Extent and duration of removal.
- (1) The removal of the ONC-AA is effective upon the date specified in the removal notice provided to the ONC-AA.
- (2) An accreditation organization that is removed as the ONC-AA must cease all activities under the permanent certification program, including accepting new requests for accreditation under the permanent certification program.
- (3) An accreditation organization that is removed as the ONC-AA is prohibited from being considered for ONC-AA status for a period of 1 year from the effective date of its removal as the ONC-AA.

Dated: November 15, 2011_____

Kathleen Sebelius,

Secretary.

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